



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)


DP BARCODE No.: D452005; FILE SYMBOL No.: 93809-L; PRODUCT NAME: Axill Solutions Clethodim 2EC; DECISION No.: 452005; PC Code(s): 121011; ACTION CODE: R300; FOOD Use: Yes; COMPANY: Axill Solutions, LLC.

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DATE OUT: August 20, 2019

SUBJECT: New End Use Product Chemistry Review
Product Name: RF2266 MPC

FROM: Dehui Duan, Ph.D.
Product Chemistry Team
CITAB/RD (7505P)


8/21/2019


8/21/19

TO: Manjula Unnikrishnan/Erik Kraft, RM 24
FHB / RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product "Axill Solutions Clethodim 2EC". In support of the registration application, the registrant has submitted a basic CSF dated April 9, 2019, and 830 series group A and group B product chemistry data with MRID No's. 50694201, 50694202, 50694203, 50694204 and 50694205. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 42750-72. CITAB has been asked to determine acceptability of the data submitted and the proposed CSF. Also determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s):

PC Code	Active Ingredient	Reg. No.	NC of AI in product (%)
121011			

2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes give the registration number of the cited product.

EPA Reg. No: 42750-72.

3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [] No

4. All inert ingredients have been screened by CITAB (Inert Team) and found to be approved for the proposed label uses - [X] Yes; [] No.

5. Confidential Statement of Formula(s):

[X] Basic - Dated: April 9, 2019; Re-submitted - Dated:

[] Alternate CSF - Dated; Re-submitted - Dated:

Alternate CSF(s) complies with 40CFR§152.43: [] Yes; [] No; [X] NA

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6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA; acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☒ Yes; ☐ No; ☐ NA

Methanol at > 4%: ☐ Yes; ☒ No; ☐ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☒ No; ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes ☐ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

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7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	50694201
830.1600	Description of materials used to produce the product		X		A	50694201
830.1650	Description of formulation process		X		A	50694201
830.1670	Discussion on the formation of impurities		X		A	50694201
830.1700	Preliminary analysis			NA		
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Basic CSF dated on April 9, 2019
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	50694202

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress,
NA = Not Applicable; U = Upgradeable.

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 8. Group B: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Light brown liquid	A	50694203
830.6314	Oxidation/Reduction	Data waiver requested	Granted	50694205
830.6315	Flammability	Data waiver requested	Denied	50694205
830.6316	Explosibility	Not Explosive	A	50694205
830.7000	pH	4.6	A	50694203
830.7100	Viscosity	9.05 Centistokes @ 25 °C 5.08 Centistokes @ 45 °C	A	50694203
830.7300	Density (units)	0.984 g/cm ³ @ 22.9 °C	A	50694203
830.6317	Storage stability Or Accelerated storage stability	The product is stable in one-year period under testing conditions.	A	50694204
830.6320	Corrosion characteristics or Accelerated corrosion characteristics	No corrosion was observed in one-year period.	A	50694204

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A. Substantial similarity to the cited product (Reg. No. 42750-72) from Product chemistry view point

- ☒ Similar
☐ Not similar, give reasons
☐ Identical
☐ Not identical
☐ Not applicable

B. Confidential Statement of formula

1. Basic CSF (dated 8-7-2019)

- ☐ Acceptable
☐ Not Acceptable
☐ Not Applicable
☒ Upgradable: Will be re-evaluated along with the data on Guideline 830.6315. May need revision if necessary.

2. Alternate CSF #1 (dated); Alternate CS #2 (Dated)

- ☐ Acceptable - #1 & #2
☐ Not Acceptable - #3, #4
☒ Not Applicable

C. Group A Product Chemistry Data

- ☒ Acceptable
☐ Not acceptable
☐ Acceptable with the exception of Guideline(s): (provide the guideline number & explain)
☐ Not required
☐ Data cited; ☐ Acceptable; ☐ Not Acceptable (give reasons)

D. Group B Product chemistry data

- ☐ Acceptable
☐ Not acceptable
☒ Acceptable with the exception of Guideline(s): 830.6315. Data of flash point/Flame extension is required as the product was labeled as "combustible".
☐ Not required
☐ Data cited; ☐ Acceptable; ☐ Not Acceptable;
☐ Waiver requests; ☐ Acceptable; ☐ Not Acceptable (give reasons)

E. Product Label/Draft Label

Recommendations – Yes ☐; No ☒

If yes, give recommendations below:

Note: Please add additional remarks if necessary for each section

